EFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Beth A. BURNSIDE et al.

Serial No.: 10/758,417 Group Art Unit: 1615

Filed: January 16, 2004 Examiner: Unknown

For: ORAL PULSED DOSE DRUG DELIVERY SYSTEM

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

a final rejection under 37 C.F.R. 1.113;
termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

☐ a final action under 37 C.F.R. § 1.113;

☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);

☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☒ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. 10/172,705, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed but not attached were cited in an international search report dated _____.

☐ Not required by 37 CFR § 1.98.

☐ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
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P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
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☐ Translation of other relevant information on foreign search report

Other Information

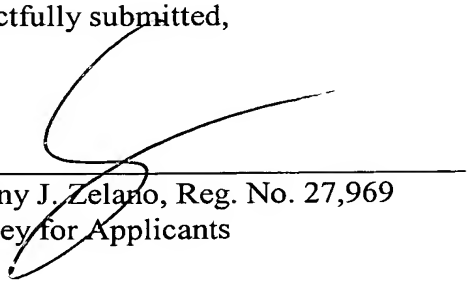
Payment of Fees Due (If Any):

☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: PHARMA-0142-C02

Date: March 7, 2005

AJZ:hlw

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known	
Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	Pharma-0142-C02

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	6,340,476	B1	Midha et al.	01/22/2002	
	A2	6,228,398	B1	Devane t al.	05/08/2001	
	A3	6,183,780	B1	Van Balken et al.	02/06/2001	
	A4	6,214,379	B1	Hermelin	04/10/2001	
	A5	6,034,101		Gupta et al.	03/07/2000	
	A6	5,945,123		Hermelin	08/31/1999	
	A7	5,885,616		Hsiao et al.	03/23/1999	
	A8	5,891,474		Busetti et al.	04/06/1999	
	A9	5,908,850		Zeitlin et al.	06/01/1999	
	A10	5,922,736		Dariani et al.	07/13/1999	
	A11	5,800,836		Morella et al.	09/01/1998	
	A12	5,824,341		Segh et al.	10/20/1998	
	A13	5,824,342		Cherukuri et al.	10/20/1998	
	A14	5,824,343		Na et al.	10/20/1998	
	A15	5,496,561		Okada et al.	03/05/1996	
	A16	5,308,348		Balaban et al.	05/03/1994	
	A17	5,260,069		Chen	11/09/1993	
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	A21	4,728,512		Mehta et al.	03/01/1988	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T_6
	B1	WO	0059481			10/12/2000		
	B2	WO	00/35450			06/22/2000		
	B3	WO	00/35426			0622/2000		
	B4	WO	99/30694			06/24/1999		
	B5	WO	97/03672			02/06/1997		
	B6	EP	0 212 747			03/04/1987		

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	A23	5,885,998		Bencherif et al.	03/1999	
	A24	5,840,329		Bai	11/24/1998	
	A25	5,837,284	A	Mehta et al.	11/17/1998	
	A26	5,616,345		Geoghegan et al.	04/01/1997	
	A27	5,395,628		Noda et al.	03/07/1995	
	A28	5,407,686		Patel et al.	04/18/1995	
	A29	5,364,620		Geoghegan et al.	11/15/1994	
	A30	5,093,200		Watanabe et al.	03/03/1992	
	A31	5,474,786		Kotwal et al.	12/12/1995	
	A32	5,312,388		Wong et al.	05/1994	
	A33	5,275,819		Amer et al.	01/04/1994	
	A34	4,723,958		Pope et al.	02/09/1988	
	A35	5,229,131		Amidon et al.	07/20/1993	
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	A37	5,051,262		Panoz et al.	09/24/1991	
	A38	5,011,694		Nuernberg et al.	04/30/1991	
	A39	5,011,692		Fujioka et al.	04/30/1991	
	A40	5,002,776		Geoghegan et al.	03/26/1991	
	A41	4,917,899		Geoghegan et al.	04/17/1990	
	A42	4,902,516		Korsatko et al.	02/20/1990	
	A43	4,891,230		Geoghegan et al.	01/02/1990	
	A44	4,894,240		Geoghegan et al.	01/1/1990	
	A45	4,871,549		Ueda et al.	10/03/1989	
	A46	4,765,989		Wong et al.	08/23/1989	
	A47	6,322,819		Burnside et al.	11/2001	
	A48	5,837,284		Mehta et al.	11/1998	

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	B7	WO	00/23055			04/27/2000		
	B8	WO	87/00044			01/15/1987		
	B9	WO	90/09168			08/23/1990		

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Sheet 3 of 4

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1	K. S. PATRICK et al., " Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit..." HUMAN PSYCHOPHARMACOLOGY, Vol. 12, pp. 527-546, 1997.	
	C2	Lisa H. BRAUER et al., " Acute Tolerance to Subjective but Not Cardiovascular Effects of d-Amphetamine in Normal, Healthy Men," JOURNAL OF CLINICAL PSYCHOPHARMACOLOGY, Vol. 16, No. 1, pp. 72-76, 1996.	
	C3	William P. MELEGA et al., "Pharmacokinetic and Pharmacodynamic Analysis of the Actions of D-Amphetamine and D-Methamphetamine on the Dopamine Terminal," THE JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, Vol., 274, No. 1, pp. 90-96, 1995	
	C4	Peter CLAUSING et al., "Amphetamine Levels in Brain Microdialysate, Caudate/Putamen, Substantia Nigra and Plasma After Dosage That Produces Either Behavioral..." THE JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, Vol. 274, No. 2, pp. 614-621, 1995.	
	C5	S.B. SPARBER et al., "Amphetamine Cumulation and Tolerance Development: Concurrent and Opposing Phenomena," PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR, Vol. 20, pp, 415-424, 1984.	
	C6	Burt ANGRIST et al., "Early Pharmacokinetics and Clinical Effects of Oral D-Amphetamine in Normal Subjects," BIOL PSYCHIATRY, Vol. 22, pp. 1357-1368, 1987..	
	C7	Gerald L. BROWN et al., "Plasma Levels of d-Amphetamine in Hyperactive Children, "PSYCHOPHARMACOLOGY, Vol. 62, pp. 133-140, 1979.	
	C8	Suk Han WAN et al.," Kinetics, Salivary Excretion of Amphetamine Isomers, and Effect of Urinary pH," CLIN. PHARMACOL. THER., pp. 585-590, May 1978.	
	C9	Gerald L. BROWN et al., "Plasma d-Amphetamine Absorption and Elimination in Hyperactive Children," PSYCHOPHARMACOLOGY BULLETIN, Vol. 14, No. 3, pp. 33-35, 1978.	
	C10	Shire Laboratory Inc.'s Complaint against Barr Laboratories based on parent U.S. Patent 6,322,819 in U.S. District Court for the Southern District of New York (Case No. 03-CV-1219(VM)(DFE))	
	C11	Barr Laboratories' Answer, Affirmative Defenses and Counterclaim in Case No. 03-CV-1219(VM)(DFE) (S.D.N.Y.)	

Examiner Signature		Date Considered	

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Sheet 4 of 4

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First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
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Attorney Docket Number	PHARMA-0142-C02

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C12	WALIA et al., Preliminary Evaluation of an Aqueous Wax, Emulsion for Controlled-Release Coating, Pharm. Dev. Tech., vol. 3, no. 1, pp. 103-113 (1998).	
	C13	BANKER et al., "Modern Pharmaceutics, eds., Marcel Dekker, Inc., New York, pg. 350 (1996)	
	C14	Gazzaniga et al., "Time-Dependent oral Delivery Systems for Colon Targeting," S.T.P. Pharma Sciences 5(1):83-88 (1995).	
	C15	WALIA et al., "Preliminary Evaluation of An Aqueous Wax Emulsion for Controlled-Release Coating," Pharmaceutical Development and Technology, 3(1):103-113 (1998).	
	C16	Gazzaniga et al., "Oral Chronotopic Drug Delivery Systems: Achievement of Time And/Or Site Specificity," Eur. J. Pharm. Biopharm, 40(4):246-250 (1994).	
	C17	POZZI et al., "The Time Clock System: A New Oral Dosage form for Fast and Complete release od Drug After a Predetermined Lag Time, " Journal of Controlled Release, 31:99-108 (1994).	
	C18	WILDING et al., "Gastrointestinal Transit and Systemic Absorption of Captopril From A Pulsed-Release Formulation," Pharmaceutical Research, 9 (5):654-657(1992).	
	C19	XIN XU et al., "Programmable Drug Delivery From An Erodible Association Polymer System," Pharmaceutical Research, 10(8):1144-1152 (1993)	
	C20	Conte et al., " Press-Coated tablets for Time-Programmed Release of Drugs," Biomaterials, 14(13):1017-1023 (1993)	
	C21	R. GURNY et al., "Pulsatile Drug Delivery Current Applications and Future Trends, pp. 112-134.	
	C22	ADDERALL XR, Package Insert, October 2001.	
	C23	Dexedrine, Spansule Capsules, Package Insert, Physicians' Desk Reference 1997.	
	C24	ADDERALL, Package Insert, May 1996, Physicians' Desk Reference 1997.	
	C25	Barr's Paragraph IV Certification against Parent U.S. Patent 6,322,819, of January 14, 2003	

Examiner Signature		Date Considered	

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